Bayer HealthCare
Pharmaceuticals

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852
http://www.fda.gov/dockets/ecomments

Carol M. Moore
Vice President
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Responsible Head / Agent

Re: Comments to Docket No. 2005N-0510
Anti-Counterfeit Drug Initiative

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Bayer HealthCare LLC, Hematology/Cardiology has reviewed the Federal Register notice regarding the Anti-Counterfeit Drug Initiative [Docket No. 2005N-0510] (Federal Register, Vol. 71, No. 7, published on January 11, 2006). Also, Bayer representatives attended the associated public workshop on February 8 and 9, 2006. Bayer supports initiatives that protect the patients using prescription medicines, including measures to deter counterfeit pharmaceuticals.

FDA is strongly encouraged to reconsider the format of the pedigree requirement of the Prescription Drug Marketing Act and its associated proposed regulations. The broad implications of industry adoption of radio-frequency identification (RFID) by 2007 appear to have been made prematurely. The technology of RFID and associated infrastructure is far from established and reliable in 2006. Radio-frequency identification is uncertain technology that clearly warrants the possible use of other tools, such as paper pedigrees or two-dimensional barcodes.

FDA is also strongly encouraged to establish universal requirements for the enforcement of the pedigree requirements. This suggestion is in harmony with the numerous presenters at the FDA Anti-Counterfeit Drug Initiative Workshop. By comparison, the state licensure of wholesale distributors has introduced more than 40 evolving systems of independent state regulations to enforce the same section of the Code of Federal Regulations (21CFR203.50). The administrative and business process burden to stay current with each state's requirements is increasing. The experience with the state wholesale distribution licenses and the suggestions from the workshop clearly indicate more uniform requirements are necessary.

Thank you for the opportunity to provide these comments on the Anti-Counterfeit Drug Initiative Docket No. 2005N-0510.

Sincerely,

Carol M. Moore
Vice President
Worldwide Regulatory Affairs
Responsible Head/Agent

CMM/AA